SUPPORTING STATEMENT
Establishing a List of U.S. Dairy Product Manufacturers/Processors
For Export to Chile
0910-0509

A. JUSTIFICATION

1. Necessity of the Information Collection

Section 701(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 371(h)) authorizes the Secretary to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of the FDA.

This proposed collection of information will address procedures being implemented by FDA to assist U.S. dairy product manufacturers and processors that wish to export dairy products to Chile. The procedures provide a solution to a trade irritant raised by the United States with Chile that U.S. dairy product manufacturers have been prevented from exporting to Chile unless each firm had undergone an individual inspection by Chilean inspectors. In the Federal Register of May 21, 2003 (68 FR 27821), FDA published a notice announcing OMB's approval of this collection of information (OMB control number 0910-0509). Since this emergency approval expires on October 31, 2003, FDA is following the normal PRA clearance procedures.

FDA has established a process to develop and maintain a list to identify the U.S. firms that ship, or intend in the future to ship, dairy products to Chile. This process comes as a result of trade discussions between the U.S. Trade Representative (USTR) and Chile that were an adjunct to the negotiations on the United States - Chile Free Trade Agreement. The Chilean government recommended in a Chilean administrative resolution, Extenta #48, dated January 9, 2003, that FDA be recognized as the competent food safety authority in the United States to identify U.S. dairy product manufacturers eligible to export to Chile.

In the Federal Register of May 23, 2003 (68 FR 28237), FDA notified the public of its new procedures available for U.S. dairy product manufacturers that wish to export to Chile in a level one guidance document pursuant to our Good Guidance Practices regulation, 21 CFR 10.115.

2. How, by Whom, and for What Purpose Information is Used

For purposes of assisting Chile in its determination of which U.S. dairy product manufacturers are eligible to export to Chile, FDA has established and intends to maintain a list identifying U.S. firms that wish to export dairy products to Chile that are subject to FDA regulatory jurisdiction and which are not the subject of an enforcement action (i.e., an injunction or seizure) or an unresolved warning letter.

FDA will collect the information by requesting that U.S. firms that want to be placed on the list send their information to FDA, pursuant to procedures that are set out in the guidance.

The information will be used as follows: FDA anticipates providing an updated list of firms to Chilean authorities on a quarterly basis, as might be necessary to place additional firms on the list. A quarterly update provides for an orderly, systematic approach for updates of "new" firms and precludes any expectation by stakeholders that a firm can be added to the list immediately after submitting a request to the agency. On the other hand, if a listed firm becomes subject to an FDA enforcement action or becomes the subject of an unresolved warning letter between the quarterly updates, that firm will be removed from the list and a revised list will be sent to the Chilean authorities as soon as practicable after the warning letter is issued or the enforcement action is initiated, e.g., within 48-72 hours. FDA also anticipates making the list available to all interested stakeholders via the agency's Internet site.

Upon developing the list of dairy product manufacturers eligible to export to Chile, FDA will share this information with Chile, pursuant to 21 CFR 20.89, under our authority to share with foreign government officials, among other types of information, investigatory records compiled for law enforcement purposes as well as any information voluntarily submitted to the FDA. Upon receipt of the list of firms from the FDA, Chile will issue an authorizing resolution and will incorporate the names of the processing plants into a list that Chile will provide to its border entry points to allow products from those listed firms to be imported.

It is not practical to only use information that has been collected for other purposes, for example, the *"The Interstate Milk Shippers (IMS) List for Grade 'A' Dairy Plants" and "The List of Dairy Plants Surveyed and Approved for USDA Grading Service."* These lists are product specific and may not include the products that the firms intend to export to Chile. Out of the actual number of firms that applied to be on the list as a result of the announcement of the guidance in the Federal Register of May 23, 2003 (68 FR 28237), 40 firms that wanted to export their products to Chile were not listed on the USDA list. The USDA list is a voluntary listing with a fee for those firms who wish to have their products graded. 31 firms were not listed on the IMS list and the USDA list. The IMS list is only for Grade A milk products and does not include non-Grade A products (e.g., cheese or ice cream).

FDA believes that it is necessary, for each initial listing of a firm, for the agency to create a complete and unique file corresponding to each request for placement on the list. The documentation contained in this file would include all relevant information necessary to demonstrate satisfaction of the minimum conditions for listing of a firm, including a copy of the most current inspection report, whether that inspection was conducted by FDA or by another regulatory entity, i.e., the U.S. Department of Agriculture or a State regulatory agency. FDA believes that a copy of the inspection report, appended to the request for placement on the list, is necessary to meet minimum documentation requirements. A firm's presence on any other list would not be sufficient to document satisfaction of the listing criteria. FDA's request to receive information from the Federal or State agency that conducted the most current inspection and, if other than FDA, a copy of the most current inspection report, will facilitate the

completion of the documentation file and the review process and will expedite the overall listing procedure.

3. Use of Improved Information Technology

The FDA continually seeks ways to reduce reporting burden. Presently, the U.S. firms may submit information by letter, facsimile, diskette, or electronic e-mail.

4. Identification of Duplication and Similar Information Already Available

As noted in Section 2, above, the information collection is a new, unique collection that is being developed for purposes of assisting Chile in its determination of which U.S. dairy product manufacturers are eligible to export to Chile. This is one of several agricultural trade issues whose resolution is tied to the United States – Chile Free Trade Agreement.

5. Small Business

This information collection may include small businesses. However, because the collection gathers the minimum information that a business is required to submit to qualify to be placed on the list, there is no way to reduce the burden on small businesses. CFSAN aids small businesses in complying with its requirements through its administrative and scientific staffs.

6. Consequences if Data Were Collected Less Frequently

The data in original submissions are submitted only once and therefore cannot be collected less frequently. A business may be required to submit updates if the submitted information changes.

7. Special Circumstances

There are no special circumstances involving this information collection.

8. Outside Consultation

Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. In the Federal Register of July 10, 2003 (68 FR 41157) FDA published a 60-day notice soliciting comments from the public. No comments were received.

In the Federal Register of April 10, 2003 (68 FR 17655), FDA published an emergency notice requesting public comment on the information collection provisions that had been submitted to OMB for emergency processing under the PRA. Four comments were received from trade associations and private industry.

Two comments expressed concern that there may be a significant delay between the time a firm submits a request to FDA to be listed and the time it is actually placed on the list for export to Chile. FDA believes that it has addressed this situation in development of its guidance. The agency developed procedures for establishing and maintaining the list to minimize the time required for placement of an eligible firm within a reasonable and predictable time after making a request to FDA to be listed.

One comment expressed concern that it is unnecessary for FDA to request, for firms already on other recognized federal government lists, the identity of the agencies that inspect the plant and the date of last inspection; plant number and copy of the last inspection notice; and, if other than an FDA inspection, a copy of the last inspection. FDA believes that it is necessary to verify the status of all firms making application to the agency to be included on the list. This process will be greatly facilitated by the information that is being requested. By placing a firm on the list, FDA will be attesting that the firm is under the regulatory jurisdiction of the FDA and is not the subject of a pending FDA judicial enforcement action or an unresolved warning letter. The lists identified by the comments, "The Interstate Milk Shippers List for Grade 'A' Dairy Plants" and "The List of Dairy Plants Surveyed and Approved for USDA Grading Service," are product specific and may not include the products the firms intend to export to Chile. This would preclude the use of these lists for some firms.

One comment noted that FDA should make use of existing lists and inspection programs when determining if a firm should be placed on the list. FDA believes that it is necessary, for each initial listing of a firm, for the agency to create a complete and unique file corresponding to each request for placement on the list. The documentation contained in this file would include all relevant information necessary to demonstrate satisfaction of the minimum conditions for listing of a firm, including a copy of the most current inspection report, whether that inspection was conducted by FDA or by another regulatory entity, i.e., the U.S. Department of Agriculture or a State regulatory agency. FDA believes that a copy of the inspection report, appended to the request for placement on the list, is necessary to meet minimum documentation requirements. A firm's presence on any other list would not be sufficient to document satisfaction of the listing criteria. FDA's request to receive information on the Federal or State agency that conducted the most current inspection and, if other than FDA, a copy of the most current inspection report, will facilitate the completion of the documentation file and the review process and will expedite the overall listing procedure.

One comment encouraged FDA to establish a system for adding plants to the list that is simple and rapid, with clear administrative rules and to consider allowing application to the list through the Internet. FDA will be using the Internet to post and maintain the list. FDA is not prepared to allow application to the list through the Internet at this time. Once the list is established and in use, FDA will consider whether it is feasible to use the Internet to receive applications.

One comment expressed concern that FDA, by establishing a list of U.S. dairy product manufacturers/processors that wish to export dairy products to Chile, would: (1) duplicate existing procedures already in place at U.S. Department of Agriculture (USDA) and State Departments of

Agriculture for obtaining export "documents" necessary for market access of U.S. dairy products into Chile; (2) cause manufacturers to have to obtain such documents from more than one federal or state agency; and (3) otherwise complicate the procedures whereby U.S. dairy manufacturers could export their products to Chile. These comments also suggested that, in the future, FDA should defer to the USDA on "negotiations" pertaining to export of U.S. dairy products to other countries.

The comments indicate that some clarification of the roles and responsibilities of U.S. government agencies is necessary. While FDA participates in many cooperative activities with U.S. States and with USDA in the area of food safety, FDA is the principal federal agency within the U.S. government responsible for the human health aspects of dairy product safety. As such, FDA is the appropriate U.S. agency to participate in discussions with foreign governments on matters relevant to the public (human) health aspects of U.S. dairy products. As stated in the April 10, 2003, Federal Register notice, Chilean authorities have recognized FDA as the competent food safety (public health) authority in the United States to identify U.S. dairy product manufacturers eligible to export to Chile. In this context, Chilean authorities will rely on FDA to list these firms and to notify Chile regularly of all U.S. dairy firms that have met the criteria to be listed. On the basis of a regularly updated list identifying firms that have applied to FDA to be listed, that are under FDA jurisdiction, and that are not the subject of a pending judicial FDA enforcement action or unresolved FDA warning letter, Chilean authorities will consider U.S. dairy products entering Chile to have satisfied public (human) health requirements. Contrary to the suggestion in the comment, no consignment-specific "document" issued by FDA must accompany any individual consignment of these dairy products.

USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for dairy product safety with respect to animal health. Many countries, including Chile, mandate that each exported consignment of U.S. dairy products be accompanied by a certificate issued by APHIS attesting to satisfaction of certain animal health requirements. With regard to the present situation, Chilean authorities will still require the consignment-specific certificate demonstrating satisfaction of certain animal health provisions. The establishment of the proposed list of U.S. dairy product manufacturers and processors by FDA will not affect the requirement for the consignment-specific APHIS certificate.

Negotiations with Chile which led to the proposal for, and decision to move forward with, the list were conducted by a U.S. government team comprised of, among others, both FDA and several USDA agencies, including APHIS and Agricultural Marketing Service.

9. Gifts

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality

Information that is trade secret or confidential commercial information is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Sensitive Information

This information collection does not involve any questions of a sensitive nature.

12. Respondent Hour Burden and Annualized Burden Cost Estimates

FDA estimates the burden of this collection of information as follows:

Table 1. -- Estimated Annual Reporting Burden[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
75[2]	1	75	1.5	112.5
8[3]	1	8	1.5	12
8[4]	1	8	0.5	4
Total				129

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] First year burden.
[3] Recurring burden.
[4]Recurring burden in reporting changes, including time reviewing collection of information and corresponding to FDA.

The estimate of the number of firms is based on the actual number of U.S. firms that applied to be placed on the list as a result of the Federal Register announcement of May 23, 2003 (68 FR 28237) regarding of the availability of a final guidance entitled "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile." The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms. We estimate that for the first year a firm will require 1.5 hours to read the Federal Register, gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list. We estimate the recurring burden in subsequent years to be 1.5 hours for a new firm to be placed on the list and 0.5 hours for reporting changes to FDA for firms already on the list.

Estimated Annualized Cost for Burden Hours

The total cost burden of 1.5 hours is attributable to completion and submission of the application. The cost is estimated to be $20 per hour for 1.5 hours per firm. FDA estimates 75 firms will make application with a total cost in the first year to be $2250.

13. Annual Cost Burden to Respondent

There are no operating, maintenance, or other continuing costs associated with this information collection.

14. Annualized Cost to the Federal Government

The annualized cost for the first year to the Federal government for the review and evaluation of letters submitted by U.S. dairy product manufacturers is $2364.75. The cost is estimated as being equivalent to 75 hours for review and evaluation for the first year at a GS-12/Step-5 salary rate of $31.53. The annualized cost for the first year to the Federal Government for inspections of U.S. dairy product manufacturers of three days (8-hour days) of inspections for eight firms at a GS-11/Step-4 salary rate of $25.54/hour for the Washington-Baltimore locality pay area for the year 2003 is estimated to be $4,903.68. For subsequent years, it is estimated to be 1 hour $31.53 for review per each new firm intending placement on the list with possibly one inspection $612.96. The cost for subsequent years is estimated to be $644.49.

15. Changes or Adjustments in Burden

The increase in burden is due to the actual number of U.S. Firms that applied to the placed on the list as a result of the Federal Register announcement of May 23, 2003 (68 FR 28237).

16. Statistical Analysis, Publication Plans, and Schedule

Not applicable.

17. Approval Not to Display Expiration Date

N/A

18. Exceptions to the Certification Statement Identified in Item 19

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.